DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M2929n

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

SEP 7 1999

Mr. William V. Lassiter
President
Precision Ear Mold Laboratories, Inc.
830 Sunshine Lane
Altamonte Springs, FL 32714

Dear Mr. Lassiter:

During an inspection of your facility located in Altamonte Springs, FL, on February 22-24, 1999, our investigator determined that your firm both manufactures and repairs Crystal Ear hearing aids and manufactures Hearing Care 2000 hearing aids. Hearing aids are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The current inspection revealed that your firm began manufacturing Crystal Ear devices on or about October 1, 1998 and shipped the first unit on November 11, 1998. Also, our inspection revealed that your firm had responsibility for repairing Crystal Ear devices returned from the field.

Additionally, your firm was observed receiving [redacted] from [redacted] Upon receipt your firm would assemble them with earmolds into finished Hearing Care 2000 hearing aids. The finished hearing aids are then shipped by your firm to Hearing Care 2000, Longwood, Florida, which in turn distributes them to the public.

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to analyze processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820. 100(a)(1). For example, not all sources of quality data (including complaints, service reports, and in-process rejects etc.) have been analyzed to identify existing and potential causes of nonconforming product.

Additionally, your firm failed to establish procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example, there is no written corrective and preventive action SOP. Your firm also failed to document all the activities required under 21 CFR 820.100. For example, there is no documentation that verification and/or validation was conducted to ensure that subject actions are effective and do not adversely affect the finished device.

2. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). For example:

   - Only about 20 Crystal Ear devices out of the 16,000 manufactured have been tested to assure they meet all specifications.

   - Test results for the Crystal Ear hearing aids demonstrate that they cannot consistently meet the total harmonic distortion specification of [redacted]

3. Failure to establish procedures for quality audits, as required by 21 CFR 820.22. For example, no SOP for internal audits, including audit schedule and audit criteria, has been established.

4. Failure to maintain device master records (DMR's) that include device specifications, as required by 21 CFR 820.180(a). For example, not all specifications for the Crystal Ear and Hearing Care 2000 hearing aids have been documented in the device master record.

5. Failure to establish and maintain procedures to adequately control environmental conditions where environment conditions could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(c). For example, firm has failed to test the room where Fonix 6500 machine is used to test hearing aids in order to ensure ambient noise, mechanical vibrations, electrical or magnetic fields do not affect test results by more than [redacted]dB, as required by the manufacturer of Fonix 6500 in its Operators Manual.

6. Failure to have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed, as required by 21 CFR 820.25(a). For example, firm's personnel qualification is inadequate in that it fails to document personnel completing critical processes (solder process, etc.) can consistently generate product, which consistently meets the required specifications.

7. Failure to validate a process with a high degree of assurance, where the results of a process cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example, the method used to mark hearing aids (label) has not been validated to demonstrate that it consistently results in the required permanent mark or label.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Please notify this office in writing within 25 days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. Any and all documentation showing plans for correction should be included with your response to this letter.

Your response should be sent to the attention of Mr. Ronald L. Swann, Dental, ENT, and Ophthalmic Devices Branch, at the above Gaither Road address.

Sincerely,

Eric Latish
Chief
Dental, ENT, and Ophthalmic Devices Branch
Division of Enforcement II
Office of Compliance
Center for Devices and Radiological Health